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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/500,376	02/08/2000	Sandra P. Chang	A-67984/RFT/DSS	2515

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EXAMINER	
FIELDS, IESHA P	
ART UNIT	PAPER NUMBER
1645	15

DATE MAILED: 07/02/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/500,376	Applicant(s) CHANG ET AL.	
	Examiner Iesha P Fields	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 37-55 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 37-55 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicants amendment filed January 24, 2002 (Paper No. 14) has been received and entered. Claims 37-55 are pending in the instant application.

Response to Amendment

The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

Priority

Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged.

Oath/Declaration

The Objection to the Oath/Declaration is **withdrawn** in view of Applicants submission of the post office address of inventor Tani Nishimura.

Claim Rejections - 35 USC § 112

1. Claims 50-55 rejected under 35 U.S.C. 112, first paragraph, is being **maintained**.

Applicant assert that the claims recite an anti-plasmodium vaccine that is comprised of an immunogenic amount of isolated p42 polypeptide and either QS-41 or ISA51 adjuvant. Applicants further assert that the p42 polypeptide claimed by the applicant is expressed by an insect cell containing a vector which encodes the polypeptide where the polypeptide is comprised of specific fragments of *Plasmodium*

falciparium surface protein gp195. Applicants further assert that the Ellis reference discusses the necessity for the proper identification of the particular protein component of a virus or microbial pathogen effective in eliciting a protective humoral immune response and does not place limits on the size of the protein component or establish what immunological properties the protein component must exhibit as conditions for the production of protective antibodies.

Applicant arguments have been carefully considered but not deemed persuasive to overcome the rejection.

As the applicants have indicated in the response, the claims recite an anti-plasmodium vaccine. The specification, while being enabling for a making an immunogenic composition comprising p42 polypeptide, it does not reasonably provide enablement for making an "anti-plasmodium vaccine". The specification provides insufficient guidance of how to use the claimed species as a vaccine. Since no working examples are set forth in the specification that the claimed species is useful for vaccination and the art teaches of the unpredictability of using such an antigen for vaccination it would be an undue burden and be unpredictable to use the broadly claimed product for vaccination. Regarding the argument that the Ellis reference does not place limits on the size of the protein component, the burden is on the applicant to prove that the product being claimed is an anti-plasmodium vaccine as recited in the claims. The Ellis reference merely teaches of the unpredictability and complexity of making such a vaccine.

Claim Rejections - 35 USC § 103

2. Claims 37-38 and 48-55 rejected under 35 U.S.C. 103(a) as being unpatentable over Holder et al further in view of Soltysik and Saul et al. is being **maintained**.

Applicants have argued that Soltysik et al. disclose the use of QS-21 as an immunological adjuvant in combination with antigens such as ovalbumin and recombinant HIV-1 envelope but fail to teach of the use of QS-21 as an immunological adjuvant in combinations with MSP p42 malaria antigen. Applicants have further argued that the MSP p42 taught by Saul et al. is not the equivalent of the claimed invention. Applicants have reasoned that since Soltysik and Saul et al. do not teach of the use of QS-21 as an immunological adjuvant in combination with MSP p42 malaria antigen there is no motivation to combine the references with the primary Holder et al. reference.

Applicant arguments have been carefully considered but not deemed persuasive to overcome the rejection.

Claims 37-38 and 48-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holder et al (the primary reference) further in view of Soltysik and Saul et al.

Holder et al. clearly teach of the merozoite major surface antigens claimed by the applicant (i.e. 83 KD, 42 KD and 19KD). The teachings of Holder et al. differ from the claimed invention in that it does not teach of a pharmaceutical composition comprising p42 polypeptide and an adjuvant such as QS-21 or ISA51. However, Soltysik and Saul et al. teach this limitations.

While the applicant has argued that Soltysik et al teach of the use of QS-21 as an immunological adjuvant in combination with other antigens (i.e. ovalbumin and recombinant HIV-1 envelope) the reference teaches in general of the use of QS-21 as an immunologic adjuvant (See Title and Abstract).

Given that 1) Holder et al. has taught of the p42 polypetide of *P. falciparum* and that 2) Soltysik et al. has taught of the use of QS-21 as an immunologic adjuvant and that 3) Saul et al. has taught of administering MSP1 and Montanide ISA adjuvant it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to make a pharmaceutical composition comprising p42 polypeptide and an adjuvant such as QS-1 or Montanide ISA. Regarding the argument that there is no motivation to combine the references, Saul et al. teaches that immunogenic compositions comprising adjuvants such as Montanide ISA720 have shown a greater immune response when compared to immunogenic compositions using traditional adjuvants such as alum.

3. Claims 37 and 39-47 rejected under 35 U.S.C. 103(a) as being unpatentable over Holder et al further in view of Murphy and Smith et al. is **maintained**.

Applicants have asserted that the crux of the invention is the combination of QS-21 or ISA-51 with MSP p42 and since Holder, Smith or Murphy do not teach this limitation, the case for *prima facie* obviousness has not been made.

Applicant arguments have been carefully considered but not deemed persuasive to overcome the rejection.

As stated above, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to make a pharmaceutical composition comprising the p42 polypeptide taught by Holder et al. with an adjuvant such as QS-21 as taught by Saul et al. Saul et al. clearly teaches of combining MSP antigen and QS-21 in a vaccine formulation (See entire article).

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

For the above reasons, it is believed that the rejections should be sustained.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Iesha P Fields whose telephone number is (703) 605-1208. The examiner can normally be reached on 7am-3:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone numbers

for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Iesha Fields

June 23, 2002

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MARK NAVARRO
PRIMARY EXAMINER